IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION – CINCINNATI

HARRY W. GRUBBS,	:	Case No. 1:19-cv-248
	:	
Plaintiff,	:	Judge Matthew W. McFarland
	:	
v.	:	
	:	
SMITH & NEPHEW, INC.,	:	
	:	
Defendant.	:	
	:	

ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

This matter is before the Court on Defendant's Motion for Summary Judgment (Doc. 22). Plaintiff filed a response in opposition (Doc. 28), to which Defendant replied (Doc. 30). Thus, this matter is ripe for review. For the reasons stated below, Defendant's Motion for Summary Judgment (Doc. 22) is **DENIED**.

FACTS

In 2017, Plaintiff underwent total hip arthroplasty (i.e., hip replacement) surgery. (Complaint, Doc. 3, Pg. ID 35.) As a part of the surgery, a Synergy Cementless Stem component ("Product"), manufactured by Defendant, was implanted. (*Id.* at Pg. ID 36; Lindenfeld Deposition, Doc. 26, Pg. ID 246, 314.) The Product is a press-fit implant, meaning that it has microscopic beads on its exterior to allow the bone to grow into the Product and "lock the prosthesis in place." (Lindenfeld Dep., Doc. 26, Pg. ID 244-49.)

Following the surgery, Plaintiff began healing normally but subsequently

experienced severe pain. (Lindenfeld Dep., Doc. 26, Pg. ID 248-50.) X-rays showed that the Product had "subsided" or slid down from Plaintiff's hip towards his knee. (*Id.* at Pg. ID 249.) At Plaintiff's three month follow up, Plaintiff's physician, Dr. Thomas Lindenfeld, noted that the Product was continuing to subside, and that Plaintiff's range of hip motion was regressing. (*Id.* at Pg. ID 250-51.) Dr. Lindenfeld opined that the Product did not incorporate into the bone as expected, resulting in the slippage and continued pain. (*Id.* at Pg. ID 252.) Consequentially, Dr. Lindenfeld referred Plaintiff to a hip specialist to get a second opinion and revision surgery. (*Id.* at Pg. ID 251; Compl., Doc. 3, Pg. ID 36.)

Prior to the initial surgery, Dr. Lindenfeld explained to Plaintiff the operation's risks and benefits, as well as alternative treatments and general problems that may occur during recovery. (Lindenfeld Dep., Doc. 26, Pg. ID 245.) Specifically, Dr. Lindenfeld explained the possible need for removal of the Product because of "pain, prominence, failure, or infection." (*Id.*) Additionally, he explained that possible further medical treatment—including revision surgery—may be required. (*Id.* at Pg. ID 245.) This conversation was documented and memorialized in a general consent form signed by Plaintiff and Dr. Lindenfeld before the surgery. (*Id.*; General Consent Form, Doc. 26-5, Pg. ID 284.)

Dr. Lindenfeld did not specifically explain to Plaintiff that the device could "loosen" as the patient's body adjusted to it. (Lindenfeld Dep., Doc. 26, Pg. ID 245.) This is because, in his 15 years of using the Product, Dr. Lindenfeld had never experienced such a failure. (*Id.*) Moreover, Dr. Lindenfeld could not articulate a specific reason why

the failure occurred. (*Id.* at Pg. ID 252.) Rather, he opined that the Product and Plaintiff's bone simply did not adapt to each other. (*Id.*)

"[M]any years ago," Defendant provided Dr. Lindenfeld with a pamphlet outlining the surgical technique for properly implanting the Product. (Lindenfeld Dep., Doc. 26, Pg. ID 253.) A list of "Warnings and Precautions" related to the Product are listed, in small print, on the last few pages of the pamphlet. (Product Pamphlet, Doc. 26-15, Pg. ID 342.) In the "Possible Adverse Effects" section, the pamphlet warns that "[l]oosening, bending, cracking, or fracture of [the] implant components may result from failure to observe the Warnings and Precautions below." (*Id.*) In the "Warning and Precautions" section, the pamphlet states:

> The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from different manufacturers. Additional Warnings and Precautions may be included in component literature.

(*Id.*) Additionally, the pamphlet warns:

> Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Various stem alignment may also be responsible.

(*Id.*)

Plaintiff originally brought this action in the Hamilton County Court of Common Pleas. (*See* Notice of Removal, Doc. 1.) The case was then removed on April 5, 2019. (*Id.*) Plaintiff brought forward numerous claims before the Court. Following this Court's Order Granting In Part And Denying In Part the Defendant's Motion to Dismiss (Doc.

10), there is one claim remaining against Defendant in this lawsuit: Inadequate Warning or Instruction in violation of the Ohio Products Liability Act § 2307.76 ("OPLA"). Defendant now moves for summary judgment, arguing that Plaintiff has failed to set forth a genuine issue of material fact in his failure to warn claim.

LAW

Courts must grant summary judgment if the record "reveals that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." *Laster v. City of Kalamazoo*, 746 F.3d 714, 726 (6th Cir. 2014) (citing Fed. R. Civ. P. 56(c)). Once the movant has met its initial burden of showing that no genuine issue of material fact remains, the nonmoving party must present "specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). To do so, they must present "significant probative evidence . . . on which a reasonable jury could return a verdict" in their favor. *Chappell v. City of Cleveland*, 585 F.3d 901, 913 (6th Cir. 2009). The court "must view the facts and any inferences that can be drawn from those facts . . . in the light most favorable to the nonmoving party." *Keweenaw Bay Indian Comm. v. Rising*, 477 F.3d 881, 886 (6th Cir. 2007). This requirement, however, does not mean that the court must find a factual dispute where record evidence contradicts wholly unsupported allegations. "The 'mere possibility' of a factual dispute is not enough." *Mitchell v. Toledo Hosp.*, 964 F.2d 577, 582 (6th Cir. 1992) (quoting *Gregg v. Allen-Bradley Co.*, 801 F.2d 859, 863 (6th Cir. 1986)).

ANALYSIS

Plaintiff brings his failure to warn claim under the OPLA. Pursuant to Ohio Rev.

Code § 2307.76, a product is defective due to inadequate warning or instruction if either of the following applies:

> (a) the manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) the manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

To prove a failure to warn claim, a plaintiff must establish that there existed: "(1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *Broyles v. Kasper Mach. Co.*, 517 F.App'x 345, 349 (6th Cir. 2013).

Defendant's sole argument is that it did not breach its duty to warn.[1] Defendant invokes the learned intermediary doctrine, pursuant to Ohio Rev. Code § 2307.76(C), claiming that it fulfilled its duty to warn of the risks of the Product by warning Plaintiff's physician. The learned intermediary doctrine establishes that a manufacturer's duty to warn is discharged if the manufacturer adequately warns the physician. *Tracy v. Merrell Dow Pharmaceuticals*, 569 N.E.2d 875, 878 (Ohio 1991). While traditionally this doctrine has been applied to prescription drugs, Ohio courts have extended the use of this doctrine

[1] In its Reply in Support of Motion for Summary Judgment, Defendant brings forward a new argument regarding the causation element of an inadequate warning claim. (*See* Doc. 30.) However, "[i]t is well established that a party 'cannot raise new issues in a reply brief; he can only respond to arguments raised for the first time in the opposition.'" *Lusk v. Lamin*, No. 2:20-cv-6064, 2022 WL 912258, at *4 (S.D. Ohio Mar 29, 2022) (citing *United States v. Campbell*, 279 F.3d 392, 401 (6th Cir. 2002)).

to prescription medical devices. *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164–65 (Ohio 2002).

However, the learned intermediary doctrine does not automatically "relieve the manufacturer of liability to the ultimate user for an inadequate or misleading warning." *Vaccariello*, 763 N.E.2d at 164. It "only provides that the warning reaches the ultimate user through the learned intermediary." *Id.* "Only when the manufacturer provides the learned intermediary with an adequate warning will the manufacturer's duty be discharged." *Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-cv-00602, 2014 WL 2874268, at *23 (S.D. Ohio June 24, 2014).

Adequacy of a warning is generally a question of fact, though it can become a question of law where the warning is accurate, clear, and unambiguous. *Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006). A warning is adequate only if "it reasonably discloses to the medical profession all risks inherent in the use of the medical device which the manufacturer knew or should have known to exist." *Seley v. G.D. Searle & Co*, 423 N.E.2d 831, 837 (Ohio 1981). A warning can be inadequate based on its content or the manner in which the warning is communicated. *Id.* The Ohio Supreme Court explained that:

> The fact finder may find a warning to be unreasonable, hence inadequate, in its factual content, its expression of the facts, or the method or form in which it is conveyed. The adequacy of such warnings is measured not only by what is stated, but also by the manner in which it is stated. A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk. A warning may be found to be unreasonable in that it was unduly delayed, reluctant in tone or lacking in a sense of urgency.

Id.

"The mere presence of . . . warnings that, if followed, may have been adequate does not eliminate the fact that a jury could find the existing warnings inadequate based upon their form, manner of expression, or lack of exigency." *Hisrich v. Volvo Cars of N. Am., Inc.*, 226 F.3d 445, 453 (6th Cir. 2000) (citing *Seley*, 423 N.E.2d at 837). In fact, "an inadequate warning may make a product as unreasonably dangerous as no warning at all." *Id.* at 452 (citing *Crislip v. TCH Liquidating Co.*, 556 N.E.2d 1177, 1181 (Ohio 1990)).

Here, Plaintiff alleges that Defendant failed to adequately warn Dr. Lindenfeld of the risk that Plaintiff's bone could fail to incorporate into the Product. (Compl., Doc. 3, Pg. ID 34-35 ("the [P]roduct's propensity to loosen and separate from the patient's hip socket").) Dr. Lindenfeld received the Product's surgical techniques pamphlet, which contained a section on "Warnings and Precautions." (Lindenfeld Dep., Doc. 26, Pg. ID 253.) The question remaining, then, is whether such warnings contained therein adequately disclosed the Product's risk of incorporation failure.

The warnings—based on their content and manner—are not so "accurate, clear, and unequivocal" such that their adequacy can be determined as a matter of law. *Meridia*, 447 F.3d at 867. The pamphlet warns that loosening of the Product "may result from failure to observe the Warnings and Precautions." (Product Pamphlet, Doc. 26-15, Pg. ID 342.) However, the "Warning and Precautions" section merely instructs a physician to warn the patient of the Product's possible surgical risks and adverse effects. (*Id.*) While the section goes on to list those risks, it fails to mention the Product's potential to loosen on its own. (*Id.*) Additionally, though the pamphlet warns that subsidence of the Product

may occur, it qualifies such failure with specific caveats. (*Id*) According to the pamphlet, subsidence occurs "in conjunction with compaction grafting procedures" or as a result of "various stem alignments." (*Id.*) As read, these warnings do not plainly communicate to a physician that the Product may simply fail to incorporate.

Moreover, the location of such warnings—in small print on the last few pages of the pamphlet—calls into question whether the warnings are conspicuous and prominent enough to adequately alert a physician of such risk. *See, e.g., Jenisek v. Highland Grp., Inc.*, No. 83569, 2004 Ohio App. LEXIS 4442, at *8 (Ohio Ct. App. 2004) (warning in product's instructions were in "very small print" and "not highlighted in color, enlarged in font or other attention-directing device"). From these considerations, reasonable minds could disagree as to the adequacy of such warnings to disclose of the Product's risk of incorporation failure.

Thus, viewing all facts and inferences in favor of Plaintiff, the non-moving party, the Court finds a genuine issue of fact exists as to the adequacy of Defendant's warnings.

CONCLUSION

For the foregoing reasons, the Court **DENIES** Defendant's Motion for Summary Judgment (Doc. 22).

IT IS SO ORDERED.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

By: _____
JUDGE MATTHEW W. McFARLAND